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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/532,832	01/04/2006	Tetsuo Miyayama	270262US0PCT	8791
22850	7590	07/08/2009		
OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314			EXAMINER FISHER, ABIGAIL L	
			ART UNIT	PAPER NUMBER
			1616	
			NOTIFICATION DATE	DELIVERY MODE
			07/08/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentdocket@oblon.com
oblonpat@oblon.com
jgardner@oblon.com

Office Action Summary	Application No. 10/532,832	Applicant(s) MIYAYAMA, TETSUO	
	Examiner ABIGAIL FISHER	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 March 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 and 8-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 and 8-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on February 25 2009 has been entered.

Receipt of Amendments/Remarks and Declaration under 37 C.F.R. 1.132 filed on February 25 2009 and March 17 2009 is acknowledged. Claim 7 was/stands cancelled. Claims 12-17 were added. Claims 1-6 and 8-17 are pending.

Claim Notes

Claim 6 pending on December 31 2007 recited "wherein said cross-linked product of poly- γ -glutamic acid or said cross-linked product of a poly- γ -glutamic acid salt has a particle size of 0.1 to 100 micrometers and an average particle size of 1 to 50 micrometer". However, currently claim 6 recites "wherein said cross-linked product of a poly- γ -glutamic acid salt has a particle size of 0.1 to 100 micrometers and an average particle size of 1 to 50 micrometers". The status of claim 6 is indicated as previously presented but the actual recitation of that claim and the resulting scope has changed.

Applicant is reminded that pursuant to 37 CFR 1.121, any amendments to the claims must recite markings to indicate changes that have been made relative to the

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immediate prior version. Additionally, claim listing must identify the status of the claims.

Therefore, when a claim is amended the correct status identifier would be currently amended.

Response to Amendment/Withdrawn Rejections

The declaration under 37 CFR 1.132 filed March 17 2009 is sufficient to overcome the rejection of claims 1-6 and 8-11 based upon JP 2001-072764 and JP'764 in view of JP 2001-354542.

The rejection of claims 1-2, 8 and 11 under 35 U.S.C. 103(a) as being unpatentable over JP 2001-072764 (JP '764, cited in the Office action mailed on 8/30/07) is **withdrawn** in light of Applicants' arguments and the Declaration filed under Rule 132 which shows that the absorption ability of poly γ -glutamic acid is different than that of poly aspartic acid.

The rejection of claims 3-4 and 9-10 under 35 U.S.C. 103(a) as being unpatentable over JP 2001-072764 in view of JP 2001-354542 (JP '542, cited in the Office action mailed on 8/30/07) is **withdrawn** in light of Applicants' arguments and the Declaration filed under Rule 132 which shows that the absorption ability of poly γ -glutamic acid is different than that of poly aspartic acid.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 6, 8-11 and 15-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 6 recites the cosmetic material comprises an oiliness agent which includes higher alcohols or esters thereof and higher fatty esters. The claim as currently written is vague and indefinite. The term "higher" is not defined in the specification or the claims. Although examples are included in the specification for these particular alcohols and esters, no indication as to what constitutes "higher" is indicated. While the terms "higher alcohols" and "higher fatty ester" are taught in the art, they are usually accompanied by a definition as to the carbon length associated with the term "higher". However, there does not appear to be a clear indication as to the lower or upper limit of the term "higher". As illustrative of the art the examiner cites, US Patent 5547602, which defines higher fatty ester to contain from about 6 to about 20 carbon atoms (column 5, lines 56-65), USPGPUB No. 20030170197 which indicates higher fatty alcohol to contain from 10 to 14 carbon atoms (paragraph 0014), US Patent No. 6278008 which indicates higher alcohols to contain carbons from 12 to 22 (column 11, lines 65-67), US Patent No. 6165454 which indicates higher alcohols to be from 10 to 18 carbons and higher fatty acid ester to be from 10 to 18 carbons (column 7, lines 6-12) and US Patent No. 4595537 which indicates higher alcohols to have 8 to 36 carbon atoms (column 3, lines 60-62). As can be seen from these references, there does not appear to be a clear definition as to the usage of the term "higher" as it relates to fatty

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alcohols or esters. Therefore, claim 6 is indefinite as the resulting claim does not clearly set forth the metes and bounds of the patent protection desired.

Claims 8-11 and 15-17 are included in the rejection as they depend on a rejected base claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Applicant Claims
2. Determining the scope and contents of the prior art.
3. Ascertaining the differences between the prior art and the claims at issue, and resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 6, 8-11 and 15-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 2001-354542 (JP '542, cited in the Office action mailed on 8/30/07) in view of Sheppard et al. (US Patent No. 4847078) as evidenced by Kunioka (Kobunshi Ronbunshu, 1993).

Applicant Claims

The instant application claims a cosmetic material comprising an oiliness agent selected from the group consisting of vegetable oils, higher alcohols or esters thereof, higher fatty esters and liquid paraffins; and a cross-linked product of a poly- γ -glutamic acid and/or a cross-linked product of a poly- γ -glutamic acid salt wherein said cross-linked product a poly- poly- γ -glutamic acid salt has a particle size of 0.1 to 100 μm and an average particle size of 1 to 50 μm .

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

JP '542 teaches cosmetic compositions comprising poly- γ -glutamic acid. The poly- γ -glutamic acid is formed via radiation. The poly- γ -glutamic acid is dissolved in solvents such as water (paragraph 009) or methanol or ethanol (paragraph 0014) and irritated with radiation to produce a cross-linked poly- γ -glutamic acid (paragraphs 8 and 9). This method is inexpensive and affords a cross-linked poly- γ -glutamic acid with greater moisturizing effect (abstract and paragraph 007). The poly- γ -glutamic acid is utilized in amount from about 0.01 to 5% by weight (paragraph 0016). The poly- γ -glutamic acid is taught as a moisturizer for skin, body and scalp (paragraph 0016). It is taught as being useful for a wide variety of external preparations such as moisturizers, face toilets, and hair gels (paragraph 0017). In a method of making the poly- γ -glutamic acid is taught as being passed through a wire gauze of 80 mesh, and after filtration freeze-dried and the resulting hydrogen absorbs water and swells (paragraph 0019).

**Ascertainment of the Difference Between Scope the Prior Art and the Claims
(MPEP §2141.012)**

While JP '542 exemplifies formation of moisturizers, JP '542 does not specify the inclusion of vegetable oils or fatty alcohols in the compositions. However, this deficiency is cured by Sheppard et al.

Sheppard et al. is directed to topical compositions. The compositions comprise about 5 to about 10% by weight of one or more topically acceptable waxes (column 2, lines 8-9). It is taught that the wax compounds are useful as emollients and humectants in topical applications. That is they aid in softening, moisturizing and lubricating the skin. The presence of these emollients/humectants promotes the production of a cream which does not irritate the skin through abrasion. Waxes taught include cetyl alcohol, stearyl alcohol and jojoba oil (column 2, lines 35-43).

***Finding of Prima Facie Obviousness Rationale and Motivation*
(MPEP §2142-2143)**

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to combine the teachings of JP '542 and Sheppard et al. and utilize a wax component in an amount from about 5 to about 10% in the topical skin formulations. One of ordinary skill in the art would have been motivated to utilize these wax components as they are taught by Sheppard et al. as providing softening, moisturizing and lubrication to topical skin applications and do not irritate the skin. One of ordinary skill in the art would therefore be motivated to add these components to the topical skin compositions taught by JP '542 in order to provide the benefits taught by

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Sheppard et al. These benefits would be advantageous to the compositions of JP '542 as the compositions of JP '542 include moisturizer applied to the skin.

Regarding claims 15-17, JP '542 teaches cross-linked poly- γ -glutamic acid. As evidenced by Kunioka, poly- γ -glutamic acid which is prepared via γ -irradiation produces a hydrogen with a specific water content of about 3500 (wt of water/wt of polymer) and a gel content that ranges from 40 to about 90% (abstract and figure 1). Kunioka therefore teaches that it was known in the art at the time of the instant invention that cross-linked poly- γ -glutamic acid is known to swell significantly (i.e. have large absorption ability) as well as the dosage of γ -irradiation changes so does the gel content. Figure 1 additionally shows that as the dosage of irradiation increases, the water content is decreased, which is the same trend seen by Applicants (Table A of Declaration filed 3/17/09).

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claims 1-5 and 12-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 2001-354542 (JP '542, cited in the Office action mailed on 8/30/07) in view of JP 2001-072764 (JP '764, cited in the Office action mailed on 8/30/07) as evidenced by Kunioka and Robinson (US Patent No. 5968500).

Applicant Claims

Applicant claims a cosmetic material comprising a cross-linked product of a poly- γ -glutamic acid and/or a cross-linked product of a poly- γ -glutamic acid salt having a particle size of 0.1 to 100 μm and an average particle size of 1 to 50 μm .

**Determination of the Scope and Content of the Prior Art
(MPEP §2141.01)**

The teachings of JP '542 are set forth above. Specifically, JP '542 teaches cosmetic compositions comprising poly- γ -glutamic acid. The poly- γ -glutamic acid is formed via radiation. The poly- γ -glutamic acid is utilized in amount from about 0.01 to 5% by weight (paragraph 0016). The poly- γ -glutamic acid is taught as a moisturizer for skin, body and scalp (paragraph 0016). It is taught as being useful for a wide variety of external preparations such as moisturizers, face toilets, and hair gels (paragraph 0017). In a method of making the poly- γ -glutamic acid is taught as being passed through a wire gauze of 80 mesh, and after filtration freeze-dried and the resulting hydrogen absorbs water and swells (paragraph 0019).

**Ascertainment of the Difference Between Scope the Prior Art and the Claims
(MPEP §2141.012)**

JP '542 does not specify a particular particle size of the poly- γ -glutamic acid. However, this deficiency is cured by JP '764

JP '764 is directed to substrates for cosmetics. A cross-linked polyamino acid is used for the base material. The cross-linked polyamino acid preferably has a backbone comprising a homopolymer of polyaspartic acid, polyglutamic acid, or polylysine (abstract, solution). It is additionally disclosed that the polyamino acid can be in the form of an alkaline metal salt, ammonium salt or amine salt (paragraph 37). It is

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disclosed that the particle size of the poly amino acid will differ according to usage and the purpose of use. When it is used as cosmetics, in order to obtain a slide nature, stretch, and a not rough feeling a size of the polyamino acid utilized is from 10 nm to 500 micrometers, preferred 100 nm to 200 micrometers and more preferred are from 1 micrometer to 100 micrometers (paragraph 0041). Exemplified are particle sizes of 100 micrometers or less (paragraph 0062). The amount of the polyamino acid is from 0.001 to 50% of the weight (paragraph 0050).

***Finding of Prima Facie Obviousness Rational and Motivation
(MPEP §2142-2143)***

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to combine the teachings of JP '542 and JP '764 and manipulate the particle size of the poly- γ -glutamic acid. One of ordinary skill in the art would have been motivated to manipulate the particle size depending on the desired end use of the cosmetic. Based on the teachings of JP '764 one of ordinary skill in the art would desire to reduce the particle size to between 1 and 100 micrometers in order to provide fine particles which do not provide a rough feel on the skin. Therefore, one of ordinary skill in the art would have been motivated to increase the particle when desiring a cosmetic with a rougher feel (for example an exfoliant) and motivated to decrease the particle size when desiring a cosmetic that has a smooth feel on the skin (such as a moisturizer). As evidenced by Robinson, polymers can be passed through various sieve screens which possess different mesh openings as well as they can be ground or crushed in order to produce desired particle sizes. A 400 mesh sieve screen produces particle sizes of 38 microns (columns 7-8, lines 65-67 and 1-8). Therefore, it is well

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within the skill of one of ordinary skill in the art to vary the mesh screen that the particles are passed through in order to manipulate the particle depending on what was desired for the particular end use.

Regarding claims 12-14, JP '542 teaches cross-linked poly- γ -glutamic acid. As evidenced by Kunioka, poly- γ -glutamic acid which is prepared via γ -irradiation produces a hydrogel with a specific water content of about 3500 (wt of water/wt of polymer) and a gel content that ranges from 40 to about 90% (abstract and figure 1). Kunioka therefore teaches that it was known in the art at the time of the instant invention that cross-linked poly- γ -glutamic acid is known to swell significantly (i.e. have large absorption ability) as well as the dosage of γ -irradiation changes so does the gel content. Figure 1 additionally shows that as the dosage of irradiation increases, the water content is decreased, which is the same trend seen by Applicants (Table A of Declaration filed 3/17/09).

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Response to Amendment

Although the previous rejections have been withdrawn, the examiner would like to address the present rejections in view of previous argument as two references, specifically JP '542 and JP '764 are utilized in the current rejections of record.

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Applicants have previously argued that the prior art does not teach the instantly claimed particle size. Applicants have argued and shown in the declaration that poly- γ -glutamic acid behaves differently than poly aspartic acid in terms of absorption ability.

Regarding the claimed particle size, the examiner maintains that based on the teaching of the art one of ordinary skill in the art would have been motivated to manipulate the particle size. One of ordinary skill in the art would expect that larger particles sizes would produce a cosmetic that possess a rougher feel where as smaller particle size would produce those that are more smooth to the touch. Therefore, depending on the end use one of ordinary skill in the art would have been motivated to manipulate the particle size. Additionally, there are various methods for producing the desired particle size. JP '542 teaches passing it through a mesh. As evidenced by Robinson there are a variety of meshes that exist for manipulation of particle size. Therefore, when desiring poly- γ -glutamic acid with a smaller particle size one of ordinary skill in the art would just have to choose a mesh of a different size with smaller openings (say a 400 mesh) in order to produce the desired particle size.

Regarding the absorption ability of the poly- γ -glutamic acid, as evidenced by Kunioka, poly- γ -glutamic acid cross-linked via γ -irradiation is known to swell significantly (i.e. have large absorption ability). Therefore, this feature of the poly- γ -glutamic acid is not unexpected.

Claims 1-2 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Irizato et al. (US Patent No. 5986042).

Applicant Claims

The instant application claims a cosmetic material comprising a cross-linked product of a poly- γ -glutamic acid and/or a cross-linked product of a poly- γ -glutamic acid salt having a particle size of 0.1 to 100 μm and an average particle size of 1 to 50 μm .

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

Irizato et al. teach cross-linked polymers. The basic polymer skeleton of the polymer is an acidic polyamino acid such as polyglutamic acid or polyaspartic acid (column 4, lines 11-15). In the case of polyglutamic acid, an alpha-bond is formed when an amino group or the like in glutamic acid or a monomer of the copolymer is bonded with the alpha-carboxyl group of glutamic acid, whereas a gamma-bond is formed with the amino group or the like is bonded with the polyglutamic acid. Alpha-bond and gamma-bonds are generally found together in polyglutamic acid (column 4, lines 65-67 to column 5, lines 1-8). When cross-linked, the cross-linked side chain may be substituted to the alpha-position or the gamma-position of the associated amide bond in the polymer backbone of the glutamic group (columns 12-13, lines 67 and 1-2). It is taught that the polyamino acid can be used in various forms such as crushed pieces. The particle size depends on the application purpose (column 83, lines 51-63). When employed in a form kneaded in a resin, a particle size ranging from 1 to 10 microns is preferred. Larger sizes are utilized when fast absorption speed and avoidance of gel

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blocking is desired (column 83-84, lines 64-67 and 1-8). The applications include sanitary products, cosmetic gels, toiletry products, etc. (columns 84-85, lines 62-67 and 1-25). Exemplified is sodium glutamate (example A1). Exemplified amount for absorbability was 0.03% (column 85, tea bag method).

**Ascertainment of the Difference Between Scope the Prior Art and the Claims
(MPEP §2141.012)**

Although Irizato et al. suggest utilizing the cross-linked polyglutamic acid in a cosmetic application, Irizato et al. does not exemplify a cosmetic comprising the cross-linked polymer. Although Irizato et al. teach that particle size of the polymer includes 1 to 10 microns, Irizato et al. does not specify the particle size of the exemplified polymers.

***Finding of Prima Facie Obviousness Rationale and Motivation*
(MPEP §2142-2143)**

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to utilize the cross-linked polyglutamic acid in a cosmetic application. One of ordinary skill in the art would have been motivated to utilize the polymer in a cosmetic application as this is one use suggested by Irizato et al. for the polymers.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to utilize the cross-linked polyglutamic acid in a particle size range of 1 to 10 microns. One of ordinary skill in the art would have been motivated to manipulate the particle size depending on the desired use as taught by Irizato et al. One particular range taught by Irizato et al. is from 1 to 10 microns for waterstopping purposes.

Therefore, when desiring a cosmetic product which possess waterstopping applicability

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(such as a sanitary napkin) it would have been obvious to one of ordinary skill in the art to utilize the polymer in a particle range from 1 to 10 microns as taught by Irizato et al.

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

It is noted that in the declaration filed on 11/16/2006, applicants showed that dispersibility of poly- γ -glutamic acid cross-linked by the electron beam radiation is higher than that of chemically cross-linked poly- γ -glutamic acid. While this evidence would be persuasive for dependent claims 9-10, this evidence would not be commensurate in scope with the other claims as independent claim 1, only requires cross-linked poly- γ -glutamic acid and does not require the cross-linking occur via radiation nor that an oil be present in the composition. Independent claim 1 additionally only requires cross-linked poly- γ -glutamic acid.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ABIGAIL FISHER whose telephone number is (571)270-3502. The examiner can normally be reached on M-Th 9am-6pm EST.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Abigail Fisher
Examiner
Art Unit 1616

AF

/Mina Haghighatian/
Primary Examiner, Art Unit 1616